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| HAYNES AND BOONE, LLP | | | GEORGE, TARA R | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/814,362 | BERRY, BRET M. |
| | Examiner | Art Unit |
| | Tara R. George | 3733 |

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 May 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12,14-31,35,37-51 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12,14-31,35,37-51 and 55-59 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 31 March 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 12/27/05, 6/07/04.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-12, 14-31,35,37-51 and 55-59 in the reply filed on 5/9/2007 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5,9,18,23-26,35,40,41,45,50,51,55 and 57-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the phrase "substantially similar shape memory alloys" in line 2.

The term substantially fails to limit the claim, thereby making the claim indefinite.

Appropriate correction is required.

Claim 9 recites the phrase "a substantially similar shape" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 18 recites the phrase "substantially polygonal cross-sectional shape" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

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Claim 23 recites the phrase "substantially equivalent" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

With regard to claims 24 and 25, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 24 recites the broad recitation "less than about", and the claim also recites "5:1" which is the narrower statement of the range/limitation. In the present instance, claim 25 recites the broad recitation "ranging between about", and the claim also recites "1:1" and "3:1" which is the narrower statement of the range/limitation. In the present instance, claims 40-47, 50, 51 and 55 recites the broad recitation "one or more", and the claim also recites "comprises a plurality" which is the narrower statement of the range/limitation.

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Claim 26 recites the phrase "substantially non-deformed state" and "substantially equivalent" in lines 1-2 and 3. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 35 recites the phrase "substantially oval-shaped" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 40 recites the phrase "substantially similar" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 45 recites the phrase "substantially similar shape" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 50 recites the phrase "substantially different" in line 4. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 51 recites the phrase "substantially different" in line 5. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 55 recites the phrase "substantially spans" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 57 recites the phrase "substantially similar" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 58 recites the phrase "substantially similar" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim 59 recites the phrase "substantially similar" in line 2. The term substantially fails to limit the claim, thereby making the claim indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,7,9,19,20 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Fehling et al. (US Pat. 6,770,094 B2).

Fehling discloses, with respect to claim 1, a disc replacement device comprising an upper shell 10; a lower shell 12; and a plurality of compressible pillars 16/18/20 and 22, each coupled to and connecting the upper and lower shells and comprising a shape memory alloy (see col. 3 lines 44-48), wherein at least one of the plurality of pillars is interiorly offset from perimeters of the upper and lower shells (see col. 3 lines 21-35). As for claims 2-5 respectively, Fehling discloses the disc replacement device, wherein the

plurality of pillars each deforms under a strain (see col. 3 lines 44-48); wherein the plurality of pillars are each superelastic within a temperature range of a live human body (see col. 3 lines 44-48); wherein the plurality of pillars are each superelastic at a temperature of above 34 degrees Celsius (see col. 3 lines 44-48); and wherein each of the plurality of pillars each comprise substantially similar shape memory alloys (see col. 3 lines 44-48). As for claim 7, Fehling discloses that at least one of the plurality of pillars comprises Nitinol (see col. 3 lines 44-48). As for claim 9, Fehling discloses that the plurality of pillars each comprise a substantially similar shape (see col. 3 lines 6-12 and figure 2). As for claims 19 and 20 respectively, Fehling discloses that at least of the plurality of pillars comprises a fillet adjacent one of the upper and lower shells (see col. 3 lines 21-35); and that at least of the plurality of pillars comprises an upper fillet adjacent the upper shell and a lower fillet adjacent the lower shell (see col. 3 lines 21-35). As for claim 26, Fehling discloses that in a substantially non-deformed state, exterior surfaces of the upper and lower shells are separated by a distance substantially equivalent to a height of a disc replaced by the disc replacement device (see col. 2 lines 55-67).

Claims 37,40-51 and 55-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (US Pub. 2007/0010887 A1).

Williams discloses, with regard to claim 37, a disc replacement device comprising a shell 14/12; and one or more fins 24 located on an outer surface of the shell and comprising a shape memory alloy (see para. 64 and para. 70). As for claim 40, Williams discloses that one or more fins comprise a plurality of fins each comprising a

substantially similar shape memory alloy (see col. 70). As for claim 41, Williams discloses that the one or more fins comprise a plurality of fins, including a first fin comprising a first shape memory alloy and a second fin comprising a second shape memory alloy, wherein the first shape memory alloy differs from the second shape memory alloy (see para. 70). As for claims 42-44, respectively, Williams discloses that at least one of the one or more fins comprises Nitinol (see para. 70); that at least one of the one or more fins comprises a copper-based alloy (see para. 70); and that a portion of at least one of the one or more fins comprises stainless steel (see para. 70). As for claims 45-49, respectively, Williams disclose the disc replacement device wherein the one or more fins comprise a plurality of fins each having a substantially similar shape (see para. 70); the one or more fins comprise a plurality of fins, including a first fin comprising a first shape and a second fin comprising a second shape, wherein the first shape differs from the second (see para. 70); wherein at least one of the one or more fins is oriented at an acute angle relative to the outer surface of the shell (see para. 70); wherein the fin oriented at the acute angle is deflectable towards the shell outer surface in response to load (see para. 70); and wherein the deflectable fin is configured to return toward a pre-deflected orientation in response to exposure to a temperature that is within a temperature range of a live human body (see para. 70). As for claim 50, Williams discloses that at least one of the one or more fins comprises an anchor portion oriented at a first angle relative to the shell outer surface; and a tip portion oriented at a second angle relative to the shell outer surface, wherein the first and second angles are substantially different (see para. 70). As for claim 51, Williams discloses that at least

one of the one or more fins comprises an anchor portion comprising a first composition; and a tip portion comprising a second composition, wherein said first and second compositions are substantially different (see para. 70). As for claim 55, Williams discloses that at least one of the one or more fins substantially spans a primary dimension of the shell outer surface (see para. 64).

Williams further discloses, with regard to claim 56, a disc replacement device comprising an upper shell 16; one or more upper fins 24 extending from an exterior surface of the upper shell, wherein at least one of the one or more upper fins comprises a first shape memory alloy (see para. 64 and para. 70); a lower shell 20; one or more lower fins 24 extending from an exterior surface of the lower shell, wherein at least one of the one or more lower fins comprises a second shape memory alloy (see para. 64 and para. 70); and one or more pillars 12 and 14 connecting the upper and lower shells wherein at least one of the one or more pillars comprises a third shape memory alloy (see para. 70). As for claims 57-59, respectively, the first shape memory alloy is substantially similar to the second shape memory alloy (see para. 70); the first shape memory alloy is substantially similar to the third shape memory alloy (see para. 70); and the second shape memory alloy is substantially similar to the third shape memory alloy (see para. 70).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12,14-18,21-25 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fehling et al. (US Pat. 6,770,094 B2) as applied to claim 1 above.

Fehling discloses that claimed invention except for, as per claim 10, wherein a first one of the plurality of pillars comprising a first shape and a second one of the plurality of pillars comprising a second shape, wherein the first shape differs from the second shape. However, it is noted that Fehling does disclose pillars 16/18/20 and 22 of different shapes and it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the pillars of Fehling wherein a first one of the plurality of pillars comprising a first shape and a second one of the plurality of pillars comprising a second shape, wherein the first shape differs from the second shape since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Fehling discloses the claimed invention except for at least of the plurality of pillars comprising a tetrahedron shape, an hour-glass shape, a rectangular prism shape, a pyramid shape, a cone shape, an irregular shape or a substantially polygonal cross-sectional shape as per claims 11, 12 and 21, and 14-18 respectively. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct at least one of the pillars of Fehling with a tetrahedron shape, an hour-glass shape, a rectangular prism shape, a pyramid shape, a cone shape, an irregular shape or a substantially polygonal cross-sectional shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of

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numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing the pillar in order to better distribute the compressive forces. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Fehling discloses the claimed invention except for the plurality of pillars including eight pillars proximate to the perimeters of the upper and lower shells and one pillar interiorly offset from the perimeters of the upper and lower shells as per claim 22. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Fehling having the plurality of pillars (see col. 3 lines 21-35) including eight pillars proximate to the perimeters of the upper and lower shells and one pillar interiorly offset from the perimeters of the upper and lower shells, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Fehling discloses the claimed invention except for at least one of the plurality of pillars having a width substantially equivalent to an average thickness of at least one of the upper and lower shells; at least one of the plurality of pillars having a height-to-width ratio of less than about 5:1; and at least one of the plurality of pillars having a height-to-width ratio ranging between about 1:1 and about 3:1, as per claims 23-25 respectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct at least one of the plurality of pillars having a width substantially equivalent to an average thickness of at least one of the upper and lower shells; at least one of the plurality of pillars having a height-to-width ratio of less than about 5:1; and at least one of the plurality of pillars having a height-to-width ratio

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ranging between about 1:1 and about 3:1, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Fehling discloses the claimed invention except for the disc replacement device having a substantially oval-shaped cross-sectional profile, as per claim 35. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the disc replacement device of Fehling with a substantially oval-shaped cross-section, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a disc replacement that better fits the anatomy of the vertebral disc space. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fehling et al. (US Pat. 6,770,094 B2) as applied to claim 1 above, and further in view of Williams et al. (US Pub. 2007/0010887 A1).

Fehling discloses the claimed invention, including the optimal temperatures of the shape memory alloy used (see col. 3 lines 44-48), except for the disc replacement device further comprising one or more fins extending from at least one of the upper and lower shells, as per claim 27; wherein one or more fins comprise a shape memory alloy, as per claim 28; wherein one or more fins are originally shaped at a temperature that is within a temperature range of a live human body, as per claim 29; wherein one or more fins are originally shaped at a temperature that is above 34 degrees Celsius, as per

claim 30; and wherein one or more fins are oriented at an acute angle relative to one of the upper and lower shells in a non-deformed state. Williams discloses the disc replacement device further comprising one or more fins 24 extending from at least one of the upper and lower shells; wherein one or more fins comprise a shape memory alloy (see para. 70); wherein one or more fins are originally shaped at a temperature that is within a temperature range of a live human body (see para. 70); wherein one or more fins are originally shaped at a temperature that is above 34 degrees Celsius (see para. 70); and wherein one or more fins are oriented at an acute angle relative to one of the upper and lower shells in a non-deformed state (see para. 70) in order to better simulate the natural movement of the vertebrae while ensuring stable fixation of the implant (see para. 9 and para. 63). It would have been obvious to one skilled in the art at the time the invention was made to create the disc replacement device of Fehling further comprising the one or more fins 24 extending from at least one of the upper and lower shells; wherein one or more fins comprise a shape memory alloy; wherein one or more fins are originally shaped at a temperature that is within a temperature range of a live human body; wherein one or more fins are originally shaped at a temperature that is above 34 degrees Celsius; and wherein one or more fins are oriented at an acute angle relative to one of the upper and lower shells in a non-deformed state, in view of Williams, in order to better simulate the natural movement of the vertebrae while ensuring stable fixation of the implant.

Claims 1,6,8 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fehling et al. (US Pat. 6,770,094 B2) and further in view of Williams et al. (US Pub. 2007/0010887 A1).

Fehling discloses the claimed invention, including the optimal temperatures of the shape memory alloy used (see col. 3 lines 44-48), except for a first one of the plurality of pillars comprising a first shape memory alloy and a second one of the plurality of pillars comprising a second shape memory alloy, wherein the first shape memory alloy differs from the second shape memory alloy, as per claim 6, wherein at least one of the plurality pf pillars comprises a copper-based alloy, as per claim 8. Williams discloses using and or incorporating a plurality of materials in the construction of a disc replacement device in order to create a device capable of simulating the natural movement of the vertebrae (see para. 9 and para. 70). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Fehling using and or incorporating a plurality of materials in the construction of a disc replacement device, in view of Williams, in order to create a device capable of simulating the natural movement of the vertebrae. It is noted that the device of claim 37 has been disclosed above and likewise, claims 38 and 39 have also been disclosed above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art of cited interest.

Any inquiry concerning this communication should be directed to Tara George whose telephone number is 571-272-3402. The examiner can normally be reached on M-F 8am-5pm. If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions about access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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